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TITLE: A Pilot Clinical Trial to Assess Percutaneous Segmental
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Centimeter

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13. ABSTRACT (Maximum 200 Words) The operative treatment of primary breast cancer has changed. The radical mastectomy has been replaced by the modified radical mastectomy. Increasingly breast-conserving operations are being accepted as the standard of care. The logical culmination of the retreat from radical mastectomy is tumor extirpation without open surgical procedures. The biological rationale for this is the same rationale that resulted in the abandonment of en bloc tumor resection in favor of breast preservation. Recent technology permits highly accurate tissue sampling of non-palpable mammographically imaged densities. An unanticipated observation associated with the use of stereotactic core biopsy was the complete removal of tumors up to 1.2 centimeters in diameter. This technology has an application to assess the ability of the devices to remove malignant tumors ≤ 1.0 centimeters in diameter with microscopically free margins assessed by subsequent open segmental mastectomy. Fifty patients with malignant tumors will undergo percutaneous segmental mastectomy with margin assessment of the percutaneous cavity, followed by open segmental mastectomy and margin assessment of the percutaneous cavity and the open segmental mastectomy margin. The proportion of patients with free margins of percutaneous segmental mastectomy cavity will be documented and the data used to determine if an NSABP randomized trial is appropriate.				
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FOREWORD

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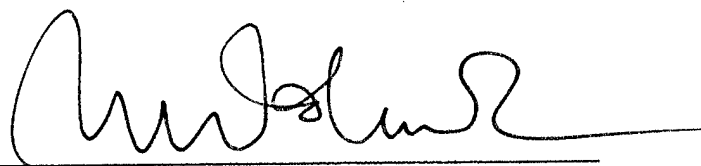
N/A In conducting research using animals, the investigator(s) adhered to the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and use of Laboratory Animals of the Institute of Laboratory Resources, national Research Council (NIH Publication No. 86-23, Revised 1985).

N/A For the protection of human subjects, the investigator(s) adhered to policies of applicable Federal Law 45 CFR 46.

N/A In conducting research utilizing recombinant DNA technology, the investigator(s) adhered to current guidelines promulgated by the National Institutes of Health.

N/A In the conduct of research utilizing recombinant DNA, the investigator(s) adhered to the NIH Guidelines for Research Involving Recombinant DNA Molecules.

N/A In the conduct of research involving hazardous organisms, the investigator(s) adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.



PI - Signature Date

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Introduction:

The logical culmination of the retreat from radical mastectomy, supported and stimulated by data from the NSABP and other studies, is the assessment of tumor extirpation without open surgical procedures. The biological rationale for this assessment is the same rationale that resulted in the abandonment of en bloc, incontinuity tumor resection in favor of breast preservation. Recent stereotactic technology permits multiple tissue core samples of mammographically imaged densities in a highly accurate fashion. An unanticipated observation associated with the use of the MammotomeTM stereotactic core biopsy device has been the complete removal of tumors up to 1.2 cm in diameters. This provocative finding and compelling ability opens a new page in the treatment of breast cancer. The ability to percutaneously remove an entire breast cancer without creating an open surgical procedure has heretofore been untested and untried in a controlled setting. The aim of this proposal is to assess the utility of percutaneous segmental mastectomy in women with mammographically imaged malignant tumors ≤ 1.0 centimeter in size; the ability to achieve a tumor free margin will be determined. If a tumor can be effectively removed percutaneously, an open surgical procedure can be eliminated and breast deformity reduced for a substantial proportion of women diagnosed with breast cancer. The cost benefit anticipated from the reduction in the number of open surgical procedures would have a major positive impact on health care economics.

Body:

Due to unforeseen circumstances, accrual to this project was severely hampered. In the time to date only one patient has accrued to this study. Therefore, the data obtained is meaningless and it will not be presented. The tasks which were outlined in the approved Statement of Work have to date not been reached.

The circumstances which led to this lack of accrual were the dynamics of a 1.6 billion dollar bankruptcy of the Allegheny Health Education and Research Foundation (AHERF) which began in July of 1998 and ended in July of 1999. Allegheny Singer Research Institute and Allegheny General Hospital are institutions within AHERF. During this time due to the severe negativism of the bankruptcy proceedings, accrual of breast cancer patients in general was affected. The number of patients with breast malignancies equal to 1 cm or less who were seen at Allegheny General Hospital was significantly less than previously seen and anticipated for accrual in this project. The majority of patients who did present with acceptable tumors had already undergone excisional resection in an open fashion making them unavailable for acceptance onto protocol. The grantee, Allegheny University of the Health Sciences (AUHS), has undergone a series of complex bankruptcy proceedings leading to a complex transaction to establish a new health-care system in the region.

Several measures have been put into place to enhance accrual. These steps include utilization of the institutional research website, distribution of the protocol and its details via the institutional protocol office to selected referral centers, announcement of the protocol in the institutional clinical trials letter and presentations of the protocol to interested professionals. Additional effort is being undertaken by the Protocol Office nursing staff to screen any eligible patients for participation in this protocol. This process will be continually assessed.

Due to the current status of this protocol, discussions with the Contract Specialist and Grants Officer, have been initiated.

Key Research Accomplishments:

None

Reportable Outcomes:

None

Conclusions:

There are no scientific conclusions at this time.

References:

None

Appendices:

None